IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA

v. **CASE NO. 1:19cr00016**

INDIVIOR INC. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.) and INDIVIOR PLC

DEFENDANTS' MEMORANDUM IN SUPPORT OF
MOTION FOR ISSUANCE OF PRE-TRIAL RULE 17(C) SUBPOENAS

Pursuant to Federal Rule of Criminal Procedure 17(c), Indivior Inc. and Indivior PLC (collectively, "Indivior") move this Court for an order authorizing the issuance of subpoenas with pre-trial return dates to five federal agencies and six state agencies that possess relevant evidentiary material that is critical to Indivior's defense. *See* Exhibits A-K. Because each of the proposed subpoenas meets the standard set forth in *United States v. Nixon*, 418 U.S. 683 (1974) for pre-trial issuance under Rule 17(c), Indivior respectfully request that the Court order the Clerk's Office to issue the attached subpoenas, which require the production of the requested materials to Indivior's counsel by December 30, 2019 to allow Indivior to inspect the materials and prepare its defense in advance of trial.

In large part, the subject of Indivior's requests in the attached Rule 17(c) subpoenas fall within the scope of the materials Indivior addressed in its Motion to Compel. *See* ECF No. 117. On October 30, 2019, Indivior filed its Objections to the Memorandum Order Denying Defendants' Motion to Compel and Motion for Bill of Particulars. *See* ECF No. 226. Due to the time necessary for full litigation of these motions and production of the critical materials in advance of trial, Indivior submits this motion without delay, and urges that these materials are

owing to the defendants both as a matter of the government's *Brady* and Rule 16 obligations and under Rule 17(c).

In particular, Indivior is now seeking, through specific and narrowly tailored requests, the pre-trial production of key materials in the possession of the specified agencies that are not only relevant, but necessary to Indivior's preparation of its defense. In all cases, the records Indivior is requesting in the subpoenas cannot otherwise be procured in advance of trial through Indivior's own due diligence. *See id.* at 699. Unlike the government, Indivior cannot simply request these materials from the agencies—through a Freedom of Information Act process or otherwise—and reasonably expect to receive the responsive materials with sufficient time to prepare for trial.[1] In addition, Indivior will be unable to "properly prepare for trial" without "production and inspection [of the responsive materials] in advance of trial." *Id.* Through its review of these agency materials, Indivior plans to designate exhibits and identify witnesses for trial, and given the expected volume of materials that will be produced in response to these

[1] The ongoing defense efforts to obtain documents from federal agencies in the government's pending case against Theranos founder Elizabeth Holmes and former CEO Ramesh Balwani is instructive on this point. In that case, the government agreed to submit the defendants' requests for documents to the Food and Drug Administration ("FDA") and the Centers for Medicare & Medicaid Services ("CMS"), and the court later ordered the agencies to comply with those requests in response to the defendants' Motion to Compel. *See* Order re Production of Documents by FDA and CMS at 5, *United States v. Holmes*, No. 5:18-cr-00258 (N.D. Cal. July 19, 2019) (ECF No. 111). Prior to any court intervention, "the FDA warned that the production of the requested materials could take a 'significant' amount of time" and later "represented that its production would take six months." *Id.* at 3-4. In ruling on the defendants' Motion to Compel, the court concluded "that FDA's anticipated six-month schedule for production [was] unacceptable" and found CMS's failure to provide any timeline for production "concerning." *Id.* at 5. The court ordered the agencies to complete their document productions within two and a half months of the order on the Motion to Compel, which would allow the defendants to obtain the documents nearly ten months in advance of trial. *See id.* at 6. In short, it was not until the court intervened that the FDA undertook the effort to produce the materials in a less than six-month timeframe, suggesting that any effort to request the materials Indivior is seeking outside of the Rule 17 process would be impractical and would only lead to delay.

subpoenas across the 11 agencies, Indivior cannot reasonably review the materials to identify exhibits and interview witnesses once trial has already commenced.

LEGAL STANDARD

"Rule 17(c) implements the Sixth Amendment guarantee that an accused have compulsory process to secure evidence in his favor," *In re Martin Marietta Corp.*, 856 F.2d 619, 621 (4th Cir. 1988), which is a guarantee "considered fundamental to the right to a fair trial," *United States v. Beckford*, 964 F. Supp. 1010, 1019 (E.D. Va. 1997). In particular, Rule 17(c) states that "[a] subpoena may order [a] witness to produce any books, papers, documents, data, or other objects the subpoena designates," and that the Court "may direct the witness to produce the designated items in court before trial" and permit inspection of the designated items by "the parties and their attorneys." Fed. R. Crim. P. 17(c). In ordering the issuance of pre-trial subpoenas to third parties under Rule 17(c), courts in this Circuit are guided by the standard set forth in *Nixon*, which requires:

> (1) that the documents are evidentiary and relevant; (2) that they are not otherwise procurable reasonably in advance of trial by exercise of due diligence; (3) that the party cannot properly prepare for trial without such production and inspection in advance of trial and that the failure to obtain such inspection may tend unreasonably to delay the trial; and (4) that the application is made in good faith and is not intended as a general 'fishing expedition.'

Nixon, 418 U.S. at 699-700. In order to meet these requirements, the requests in a pre-trial Rule 17(c) subpoena "must clear three hurdles: (1) relevancy; (2) admissibility; [and] (3) specificity." *Id.* at 700; *see also In re Martin*, 856 F.2d at 621 (affirming the district court's application of the three *Nixon* factors in ordering the production of materials subpoenaed under Rule 17(c)). To be clear, *Nixon* does not require that the materials sought through Rule 17(c) subpoenas actually be used in evidence; "[i]t is only required that a good faith effort be made to obtain evidence" through the Rule 17 process. *In re Martin*, 856 F.2d at 622.

ARGUMENT

Each of the proposed subpoenas attached to this motion include requests that meet *Nixon*'s standards, and seek materials that are critical to Indivior's preparation of its defense. For each subpoena, Indivior has narrowly tailored its requests to seek only the relevant information that it knows to be in the possession of these agencies on account of (1) the agencies' clearly defined roles in the oversight and/or regulation of the controlled pharmaceutical supply chain or (2) the information contained in documents produced by the government in this case or in other publicly available materials. Indivior is not seeking general discovery from these agencies or engaging in a fishing expedition. It is simply requesting the specific, critical information it needs to prepare its defense. Indeed, without the production of the requested information from these key agencies, there will be significant gaps in the evidence Indivior is able to offer at trial, both in terms of documentary evidence and witnesses employed by the relevant agencies, thereby undercutting Indivior's right to a fair trial.

I. Subpoena Directed to the Drug Enforcement Administration ("DEA")

In the attached subpoena directed to the DEA (Exhibit A) Indivior is seeking:

- (1) The complete DEA file for Dr. [redacted] (DEA Number: [redacted]), including the records relating to any audit or investigation of and disciplinary action taken against Dr. [redacted] and any reports submitted by pharmacies to the DEA regarding prescriptions written by Dr. [redacted];
- (2) The complete DEA file for Dr. [redacted] (DEA Number: [redacted]), including the records relating to any audit or investigation of and disciplinary action taken against Dr. [redacted] and any reports submitted by pharmacies to the DEA regarding prescriptions written by Dr. [redacted];
- (3) The complete DEA file for Dr. [redacted] (DEA Number: [redacted]), including the records relating to any audit or investigation of and disciplinary action taken against Dr. [redacted] and any reports submitted by pharmacies to the DEA regarding prescriptions written by Dr. [redacted];
- (4) The complete DEA file for Dr. [redacted] (DEA Number: [redacted]), including the records relating to any audit or investigation of and disciplinary action

taken against Dr. [redacted] and any reports submitted by pharmacies to the DEA regarding prescriptions written by Dr. [redacted];

- (5) The complete DEA file for Dr. [redacted] (DEA Number: [redacted]), including the records relating to any audit or investigation of and disciplinary action taken against Dr. [redacted] and any reports submitted by pharmacies to the DEA regarding prescriptions written by Dr. [redacted];

- (6) The complete DEA file for Dr. [redacted] (DEA Number: [redacted]), including the records relating to any audit or investigation of and disciplinary action taken against Dr. [redacted] and any reports submitted by pharmacies to the DEA regarding prescriptions written by Dr. [redacted]; and

- (7) The complete DEA file for Dr. [redacted] (DEA Number: [redacted]), including the records relating to any audit or investigation of and disciplinary action taken against Dr. [redacted] and any reports submitted by pharmacies to the DEA regarding prescriptions written by Dr. [redacted].

These requests are tied directly to the government's claim in the Indictment that, through its marketing, Indivior somehow aided and abetted these physicians in prescribing and dispensing Suboxone Film in a "careless and clinically unwarranted manner." *See* Indictment ¶ 31, p. 26, ¶¶ 97-143 (ECF No. 3). The DEA is the agency that by law registers physicians to prescribe opioids and has the authority to monitor the prescribing activity of registered physicians and take action against registered physicians who are prescribing illegally.[2] The action or inaction of the DEA as to these physicians, which will be reflected in the requested files, is highly relevant to the question of the propriety of the physicians' prescribing practices and thus, critical to Indivior's defense.

As Indivior has explained in other filings submitted to this Court, it is immaterial to the question of relevance whether the DEA actually ever investigated these physicians. If it did, and

[2] *See, e.g.*, 21 C.F.R. 1301.36; 21 U.S.C. § 824(a). "Under the CSA, DEA has the authority to deny, suspend, or revoke a DEA registration upon a finding that the registrant has," among other things, "committed an act which would render the DEA registration inconsistent with the public interest." Drug Enforcement Admin., Practitioner's Manual: An Informational Outline of the Controlled Substances Act, 11 (2006). Suspension of any registration can be done immediately with the issuance to show cause in any case in which "there is an imminent danger to the public health or safety." 21 C.F.R. 1301.36(e).

there was no finding or action taken, that information will show that the agency charged with monitoring such activities did not view the physicians' prescribing practices to be actionable. If it did not, that too shows a lack of concern regarding the physicians' methods of prescribing. In this way, the evidence requested from the DEA will be admissible as a record of the DEA's regularly conducted activity as to these physicians or to show the absence of any record of such activity. *See* Fed. R. Evid. 803(6). Moreover, Indivior has narrowly tailored its requests to the DEA to a set of seven specific physicians based on a good-faith assessment that the government is alleging that these physicians engaged in careless prescribing practices, including the four physicians specifically identified as Doctors A through D in the Indictment.

II. Subpoena Directed to the Substance Abuse and Mental Health Services Administration ("SAMHSA")

Whereas the DEA is responsible for the registration and monitoring of physicians prescribing controlled substances generally, SAMHSA is responsible for overseeing a physician's prescribing of buprenorphine-containing products under the Drug Addiction Treatment Act ("DATA") of 2000.[3] In light of SAMHSA's critical oversight role, Indivior has requested in the attached subpoena directed to SAMHSA (Exhibit B):

- (1) The records reflecting the SAMHSA review and approval of Dr. [redacted]'s (DEA Number: [redacted]) DATA 2000 practitioner waiver and patient limit increase, any consideration of revoking such waiver and patient limit increase, and any audits or investigations completed with regard to Dr. [redacted];
- (2) The records reflecting the SAMHSA review and approval of Dr. [redacted]'s (DEA Number: [redacted]) DATA 2000 practitioner waiver and patient limit increase, any consideration of revoking such waiver and patient limit increase, and any audits or investigations completed with regard to Dr. [redacted];
- (3) The records reflecting the SAMHSA review and approval of Dr. [redacted]'s

[3] Substance Abuse & Mental Health Servs. Admin., Practitioner and Program Data, https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/practitioner-program-data (last visited Nov. 18, 2019).

(DEA Number: [redacted]) DATA 2000 practitioner waiver and patient limit increase, any consideration of revoking such waiver and patient limit increase, and any audits or investigations completed with regard to Dr. [redacted];

- (4) The records reflecting the SAMHSA review and approval of Dr. [redacted]'s (DEA Number: [redacted]) practitioner waiver and patient limit increase, the records reflecting the timing and basis of SAMHSA's decision to remove Dr. [redacted] from its Buprenorphine Practitioner Locator, and the records reflecting any audits or investigations completed with regard to Dr. [redacted];

- (5) The records reflecting the SAMHSA review and approval of Dr. [redacted]'s (DEA Number: [redacted]) DATA 2000 practitioner waiver and patient limit increase, any consideration of revoking such waiver and patient limit increase, and any audits or investigations completed with regard to Dr. [redacted];

- (6) The records reflecting the SAMHSA review and approval of Dr. [redacted]'s (DEA Number: [redacted]) DATA 2000 practitioner waiver and patient limit increase, any consideration of revoking such waiver and patient limit increase, and any audits or investigations completed with regard to Dr. [redacted];

- (7) The records reflecting the SAMHSA review and approval of Dr. [redacted]'s (DEA Number: [redacted]) DATA 2000 practitioner waiver and patient limit increase, any consideration of revoking such waiver and patient limit increase, and any audits or investigations completed with regard to Dr. [redacted]; and

- (8) The records reflecting SAMHSA's policies regarding the addition or removal of physicians from its Buprenorphine Practitioner Locator.

Here again, Indivior's requests are tied directly to the government's claim in the Indictment that, through its marketing, Indivior somehow intentionally aided and abetted purportedly careless prescribing and dispensing practices of these physicians. *See* Indictment ¶ 31, p. 26, ¶¶ 97-143. The action or inaction of SAMHSA as to these physicians, which will be reflected in the requested files, is highly relevant to the question of the propriety of the physicians' prescribing practices and thus, critical to Indivior's defense.

As with the DEA requests, this evidence requested from SAMHSA will be admissible as a record of SAMHSA's regularly conducted activity as to these physicians or to show the absence of any record of such activity. *See* Fed. R. Evid. 803(6). Indivior has narrowly tailored its requests to the same seven physicians, including the physicians identified as Doctors A

through D in the Indictment, based on a good-faith assessment that the government will allege that these physicians engaged in careless prescribing practices. Indivior has also requested the records reflecting SAMHSA's policies regarding the addition or removal of physicians from its Buprenorphine Practitioner Locator, an online listing of "practitioners authorized to treat opioid dependency with buprenorphine" in each state.[4] This information is squarely relevant to Indivior's defense. The government has charged Indivior with a crime for retaining on its referral list doctors who were at the same time included on SAMHSA's list of authorized practitioners.

In addition to the physician-specific requests, Indivior has also requested from SAMHSA:

- (9) The records reflecting SAMHSA's analysis leading to the conclusion incorporated in the "Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: A Treatment Improvement Protocol TIP 40" published to the SAMHSA website that buprenorphine dosing at amounts up to 32 mg per day is recommended for certain patients and the time period during which this guidance was available on SAMHSA's website;

- (10) The records reflecting SAMHSA's analysis leading to the conclusion published on the SAMHSA website until at least 2017 in the publication titled, "Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs: A Treatment Improvement Protocol TIP 43" that while most buprenorphine "patients are likely to remain stable on 12 to 24 mg per day, . . . some might need dosages of up to 32 mg per day" and the time period during which this guidance was available on SAMHSA's website;

- (11) The records reflecting SAMHSA's analysis leading to the statement published as a part of its "Federal Guidelines for Opioid Treatment Programs" in 2015 that "[u]nless clinically indicated, there should be no limits on patients' duration of treatment or dosage level of medication" and the time period during which this guidance has been available on SAMHSA's website; and

- (12) The evidence supporting SAMHSA's determination that increasing the waivered physician patient limit to 275 would help prevent diversion of buprenorphine, as

[4] *Buprenorphine Practitioner Locator*, SAMHSA, https://www.samhsa.gov/medication-assisted-treatment/practitioner-program-data/treatment-practitioner-locator (last visited Nov. 18, 2019).

reflected in the final rule published at 81 Fed. Reg. 44711 (July 8, 2016).

In the Indictment, the government claims that doses of buprenorphine exceeding 24 milligrams were at no time shown to provide any clinical advantages. *See, e.g.*, Indictment ¶¶ 14, 20, 97, 99. As a part of the purported scheme in which the Indictment alleges that Indivior aided and abetted the careless prescribing practices of certain physicians, the Indictment claims that Indivior did this, in part, by aiding physicians who were at times prescribing daily doses exceeding 24 mgs of buprenorphine. The analysis underlying SAMHSA's publicly stated conclusions regarding dosing levels above 24 mgs are thus highly relevant to the question of whether Indivior should have regarded this as a "careless" prescribing practice.

Similarly, the Indictment alleges that these same physicians engaged in careless practices by purportedly prescribing buprenorphine-containing drugs to more patients at a time than allowed under DATA. Putting to one side the question of how these patient limits were actually calculated, it is relevant to the question of whether Indivior could have intentionally aided or abetted purported "careless" prescribing that the federal agency responsible for overseeing physicians' prescribing under DATA believed that the lack of access to buprenorphine could actually lead to buprenorphine diversion.[5] Indivior has thus requested the evidence supporting SAMHSA's determination that an increased patient limit could help prevent diversion of buprenorphine, to show the lack of any intent to aid these physicians in careless prescribing.

For each of these additional requests relevant to the physicians' prescribing practices,

[5] *See* Medication Assisted Treatment for Opioid Use Disorders, 81 Fed. Reg. 44711 (July 8, 2016) (final rule) ("Given the evidence supporting buprenorphine-based MAT as an effective treatment for opioid use disorder and the magnitude of the opioid crisis, this rule is intended to increase access to buprenorphine-based MAT, prevent diversion, and ensure quality services are provided."); *see also* Medication Assisted Treatment for Opioid Use Disorders, 81 Fed. Reg. 17639, 17655 (Mar. 30, 2016) (proposed rule) (explaining "that studies have found that the motivation to divert buprenorphine is often associated with lack of access to treatment" and that the proposed rule "could, in some cases, reduce diversion because of improved access to high-quality, evidence based buprenorphine treatment").

Indivior has focused solely on materials known to exist based on SAMHSA's publicly available statements regarding these key issues. In its requests, Indivior has clearly identified each of those statements to guide SAMHSA's collection of the records and to prevent any undue burden in responding to the subpoena.

III. Subpoena Directed to the Food and Drug Administration ("FDA")

In the attached subpoena directed to the FDA (Exhibit C), Indivior's first request is tied directly to the claim in the Indictment that between 2010 and 2019, Indivior distributed certain marketing materials containing purportedly false and fraudulent representations regarding Suboxone Film. *See* Indictment ¶ 76, p. 40. The FDA's Office of Prescription Drug Promotion ("OPDP"), previously known as the Division of Drug Marketing, Advertising and Communications, is responsible for "reviewing prescription drug advertising and promotional labeling to ensure that the information contained in these promotional materials is not false or misleading."[6] Thus, Indivior has requested from the FDA:

- (1) The records reflecting the FDA Office of Prescription Drug Promotion's (formerly known as the Division of Drug Marketing, Advertising and Communications) receipt and review of the following promotional or marketing materials for Suboxone Film submitted by Reckitt Benckiser Pharmaceuticals Inc. ("RBPI") or Indivior Inc. between 2010 and 2019:

    a. Any submissions referencing Suboxone Film "Helping Address Public Health Needs;"

    b. Any submissions stating that Suboxone Film could "Help Address Misuse and Abuse";

    c. Any submissions stating that Suboxone Film "Can Be Part of the Solution" to "misuse," "diversion and abuse," and "unintentional pediatric exposure";

    d. Any submissions stating that "Nearly half of Suboxone Film prescribers surveyed cited 'potential for reduction of abuse and diversion' as a reason to

[6] *The Office of Prescription Drug Promotion (OPDP)*, FDA, https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp (last visited Nov. 18, 2019).

prescribe vs Suboxone Tablet";

e. Any submissions including a chart with the heading, "Suboxone Film—Helping to Reduce the Risk of Pediatric Exposure";

f. Any submissions including a chart with the heading, "Suboxone . . . Film—associated with lower rates of diversion and abuse . . ."; and

g. Any submissions referencing data showing "fewer pediatric exposures for Suboxone Film vs Suboxone Tablet."

The specified marketing materials included in this request are tailored directly to those referenced in the Indictment. *See, e.g.*, Indictment ¶ 76. And the records reflecting OPDP's review of these materials, which is done for the very purpose of determining whether they are false or misleading, is clearly relevant to Indivior's defense of the government's claim that the documents contained "materially false and fraudulent statements and representations." *See id.*

In related requests, Indivior is seeking from the FDA the records tied to its review of certain Risk Evaluation and Mitigation Strategy ("REMS") assessment reports and Risk Minimization Action Plan ("RiskMap") reports. Specifically, Indivior is requesting:

- (2) The records reflecting the FDA Office of Surveillance and Epidemiology review of Indivior's annual Risk Evaluation and Mitigation Strategy ("REMS") Assessment Reports submitted between 2009 and 2019 (including all such reports submitted by RBPI);

- (3) The annual assessment reports submitted between 2013 and 2019 by the Buprenorphine-containing Transmucosal products for Opioid Dependence ("BTOD") REMS group and related reviews by the FDA and its Office of Surveillance and Epidemiology; and

- (14) The records reflecting the review and analyses of RiskMap reports submitted by RBPI/Indivior to the FDA related to the Suboxone Tablet, including but not limited to the analyses of unintended pediatric exposure, misuse and abuse, and physician and patient understanding of risks of misuse and abuse.

In certain circumstances, the FDA requires pharmaceutical manufacturers to develop and assess a REMS to promote the safe use of a particular pharmaceutical. For example, the stated purpose of the current REMS for Suboxone is to "[m]itigate the risks of accidental overdose, misuse and

abuse" and to "[i]nform prescribers, pharmacists, and patients of the serious risks associated" with the drug.[7] At periodic intervals, manufacturers subject to a REMS submit an assessment report to the FDA "that includes analysis, findings and conclusions related to whether the REMS is meeting its goals and what if any, modification may be needed."[8] The FDA then "reviews the REMS assessment reports, determines if the REMS assessment report is complete, if the REMS is meeting its goals, and if the REMS goals, elements, tools or assessment plan should be modified."[9] Prior to the implementation of the REMS process, the FDA would occasionally ask manufacturers to develop a RiskMap to mitigate risks associated with certain drug products.[10] As with REMS, pharmaceutical manufacturers would generally submit progress reports to the FDA in connection with a RiskMap addressing the evaluation of the relevant objectives.[11]

The records reflecting the FDA's review and analysis of these submissions will reveal its own knowledge and view of the comparative safety risks associated with the Suboxone Tablet and Suboxone Film. This information is, of course, highly relevant to whether Indivior's statements regarding the comparative safety of film and tablets and the relative risk of pediatric exposure and diversion were actually false as alleged in the Indictment. As with the other requests, Indivior has limited this to a specific, narrow category of submissions to the FDA.

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[7] *Approved Risk Evaluation and Mitigation Strategies (REMS)*, FDA, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=352 (last updated Oct. 26, 2018).

[8] *Frequently Asked Questions (FAQs) about REMS*, FDA, https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems (last updated Jan. 26, 2018).

[9] *Id.*

[10] *FDA's Role in Managing Medication Risks*, FDA, https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/fdas-role-managing-medication-risks (last updated Jan. 26, 2018).

[11] Food & Drug Admin., Guidance for Industry Development and Use of Risk Minimization Action Plans (Mar. 2005), https://www.fda.gov/media/71268/download.

Next, Indivior has requested from the FDA certain key materials underlying the agency's assessment of the Citizen Petition submitted by Indivior (then known as RBPI) in 2012. After determining through a statistical analysis that a switch to film packaging correlated with a drop in rates of pediatric exposure, Indivior submitted a Citizen Petition asking that the FDA require all manufacturers of buprenorphine products to implement unit-dose, child-resistant packaging as a matter of public safety to reduce the risk of child poisonings.[12] Although the FDA ultimately denied Indivior's Citizen Petition, it agreed with many points raised by the company, and all four of the FDA divisions and offices that considered the issue concluded that "Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging."[13] Consistent with these conclusions, at an April 2013 meeting among generic buprenorphine manufacturers, the FDA informed the group that it viewed "the packaging of buprenorphine-containing products as a significant safety issue in regards to pediatric exposure," and recommended that each of the group's members voluntarily switch to unit-dose packaging for their buprenorphine-containing products.[14]

Indivior is therefore requesting in the subpoena to the FDA:

- (4) The records reflecting the analysis and review underlying the conclusion reached by the FDA's Office of Surveillance and Epidemiology, as expressed and reviewed by Kellie Taylor and Gerald Dal Pan in connection with the office's assessment of the 2012 Reckitt Benckiser Pharmaceuticals Inc. Citizen Petition, that "Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than

[12] Citizen Petition from Tim Baxter, Glob. Medical Dir., Reckitt Benckiser Pharm., Inc. to Food & Drug Admin. 3 (Sept. 25, 2012).

[13] Citizen Petition Response from Food & Drug Admin. Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology (Feb. 14, 2012) (RBP0114_19147715); Citizen Petition Response from Division of Anesthesia, Analgesia, and Addiction Products (Dec. 6, 2012) (RBP0114_19147735); Citizen Petition Response from Division of Medication Error Prevention and Analysis (Feb. 14, 2013) (RBP0114_19147756-57); Citizen Petition Response from Division of Epidemiology (Feb. 14, 2013) (RBP0114_19147802) (collectively, "Citizen Petition Responses").

[14] Buprenorphine Prod. Mfrs. Grp. (BPMG), Meeting Minutes of FDA Call on BTOD REMS Submission 3-5 (Apr. 9, 2013).

Suboxone tablets in multi-dose packaging" and that "the role of unit-dose packaging and child-resistant closures are well accepted measures of preventing accidental pediatric exposures to drug products." This will include all underlying data reviewed in assessing the comparative pediatric exposure risk;

- (5) The records reflecting the analysis and review underlying the conclusion reached by the FDA's Division of Anesthesia, Analgesia, and Addiction Products, as expressed and reviewed by Celia Winchell, Rigoberto Roca, and Bob Rappaport in connection with the division's assessment of the 2012 Reckitt Benckiser Pharmaceuticals Inc. Citizen Petition, that "Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging." This will include all underlying data reviewed in assessing the comparative pediatric exposure risk;

- (6) The records reflecting the analysis and review underlying the conclusion reached by the FDA's Division of Medication Error Prevention and Analysis, as expressed and reviewed by Kellie Taylor, Sue Liu, and Carol Holquist in connection with the division's assessment of the 2012 Reckitt Benckiser Pharmaceuticals Inc. Citizen Petition, that "Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging." This will include any underlying data reviewed in assessing the comparative pediatric exposure risk;

- (7) The records reflecting the analysis and review underlying the conclusion reached by the FDA's Division of Epidemiology, as expressed and reviewed by Christian Hampp in connection with the division's assessment of the 2012 Reckitt Benckiser Pharmaceuticals Inc. Citizen Petition, that "Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging" and that "if there is a return to market dominance of buprenorphine/naloxone tablets without unit-of use packaging, pediatric exposures are likely to rise." This will include any underlying data reviewed in assessing the comparative pediatric exposure risk;

- (8) The records reflecting the guidance provided to generic buprenorphine manufacturers regarding the FDA's classification of the packaging of buprenorphine-containing products as a "significant safety issue in regards to pediatric exposure," including the FDA's recommendation to switch to unit-dose packaging for buprenorphine-containing products. This will include, but not be limited to, the documents reflecting the communications or analysis conducted in advance of and in connection with the guidance provided to generic buprenorphine manufacturers during the April 9, 2013 meeting of the Buprenorphine Product Manufacturers Group on the BTOD REMS Submission; and

- (9) The meeting materials and minutes from meetings or calls of the Buprenorphine Product Manufacturers Group in 2013.

In light of the views expressed by the FDA on the issue of pediatric exposure, these records are

directly relevant to, and indeed will directly undermine, the government's claims that Indivior made *false* statements that Suboxone Film was safer and less susceptible to pediatric exposure than other similar drugs. *See, e.g.*, Indictment ¶ 1.

Of course, the government has also alleged in the Indictment that on or about March 29, 2010, the FDA wrote a letter to RBPI in which it expressed doubt that the packaging for Suboxone Film would "provide[] meaningful incremental protection against pediatric exposure," at least in part because of the lack of data addressing how patients would store Suboxone Film. Indictment ¶ 27. Although this occurred prior to the time Indivior observed the higher rate of pediatric exposure by Suboxone Tablet compared to Suboxone Film, Indivior has also requested:

- (11) The records reflecting the FDA analysis of Suboxone Film packaging that led to its March 29, 2010 letter to RBPI.

These records will indicate the depth of analysis undertaken by the FDA to develop this statement and the disparate views of any divisions or offices on the same issue. This context is not only relevant, but necessary to understanding the FDA's full assessment of the pediatric exposure issue, particularly in light of the agreement by four FDA divisions and offices just three years later that "Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging."[15]

In the subpoena directed to the FDA, Indivior is also requesting:

- (10) The records reflecting the FDA review or analysis of the dosage amounts included in the approved labels for the Suboxone Tablet and Suboxone Film.

As noted above, the Indictment claims that Indivior allegedly aided and abetted the careless prescribing practices of physicians who were at times prescribing daily doses exceeding 24 mgs of buprenorphine. It is thus relevant to Indivior's defense what the FDA reviewed and analyzed

[15] *See supra* note 13.

with regard to dosing amounts at the time it approved the labels for the Suboxone Tablet and Suboxone Film. Given that SAMHSA, another operating division of the Department of Health and Human Services, has at various points indicated that dosing at amounts up to 32 mg/day is recommended for certain patients, the FDA's consideration of the dosing amounts is similarly relevant to the question of whether Indivior should have regarded dosing exceeding 24 mgs as a "careless" prescribing practice.

Finally, Indivior is requesting that the FDA produce:

- (12) The records reflecting the support and basis for the FDA's policy, finalized in February 2019, "to encourage widespread innovation and development of new buprenorphine treatments for opioid use disorder"; and

- (13) The records relating to the congressional testimony of FDA Commissioner Scott Gottlieb in October 2017 and any other FDA personnel regarding the expanded utilization of buprenorphine treatments.

Throughout the Indictment, the government has attempted to paint Indivior as a contributor to the opioid epidemic, when in fact Indivior's top priority has always been the treatment of patients struggling with opioid addiction. The records underlying the FDA's policy and its commissioner's testimony encouraging expanded development and utilization of buprenorphine treatments is a relevant part of the larger story about the treatments Indivior has developed, and an essential aspect of Indivior's defense in this case. Here again, Indivior has narrowly tailored its request to the records underlying two specific, publicly available announcements of the FDA's support for buprenorphine treatments.

IV. Subpoena Directed to the Centers for Disease Control ("CDC")

Like the FDA, the CDC has expressed views on the impact unit-dose packaging has had on pediatric exposure that are directly relevant to Indivior's defense regarding the alleged falsity of Indivior's purported statements addressing the safety of Suboxone Film. In 2016, multiple CDC employees, together with others from the FDA, published findings from a study regarding

the rates of pediatric emergency room visits for buprenorphine/naloxone ingestions, which dropped by two thirds when prescriptions dispensed in unit-dose packaging increased to over 80%.[16] The government interviewed and obtained select documents from just one of these CDC employees, but did not collect all the records relevant to Indivior's defense or speak to any of the other CDC employees. Moreover, the memorandum from the government's interview of one of the authors of the study, Dr. Daniel Budnitz, explains that Dr. Budnitz requested that Indivior (at the time known as RBPI) attend a CDC-sponsored meeting of the Prevention of Overdoses and Treatment Errors in Children Taskforce ("PROTECT") to explain its decision to move to unit-dose packaging, hoping that "other drug manufacturers would move toward unit-dose packaging in their products to reduce child exposures."[17] Indivior is therefore requesting in its subpoena directed to the CDC (Exhibit D):

- (1) The records reflecting the analysis of and views expressed by Daniel S. Budnitz, MD, within the CDC's Division of Healthcare Quality Promotion, regarding the impact of unit-dose packaging of buprenorphine products on pediatric exposure and the findings addressed in the October 21, 2016 publication titled, "Pediatric Emergency Department Visits for Buprenorphine/Naloxone Ingestion – United States, 2008-2015";

- (2) The records reflecting the analysis of and views expressed by Maribeth C. Lovegrove, MPH, within the CDC's Division of Healthcare Quality Promotion, regarding the impact of unit-dose packaging of buprenorphine products on pediatric exposure and the findings addressed in the October 21, 2016 publication titled, "Pediatric Emergency Department Visits for Buprenorphine/Naloxone Ingestion – United States, 2008-2015";

- (3) The records reflecting the analysis of and views expressed by Mathew R.P. Sapiano, PhD, within the CDC's Division of Healthcare Quality Promotion, regarding the impact of unit-dose packaging of buprenorphine products on pediatric exposure and the findings addressed in the October 21, 2016 publication titled, "Pediatric

[16] Daniel S. Budnitz, et al., Centers for Disease Control and Prevention, Notes from the Field: Pediatric Emergency Department Visits for Buprenorphine/Naloxone Ingestion—United States, 2008-2015, 65 Morbidity & Mortality Wkly. Rep. 1148 (2016).

[17] Department of Health and Human Services, Office of Inspector General, Report of Interview of Captain Daniel Budnitz, 2 (Mar. 13, 2019) (M2085-M2089_0000009).

Emergency Department Visits for Buprenorphine/Naloxone Ingestion – United States, 2008-2015";

- (4) The records reflecting the analysis of and views expressed by Scott R. Kegler, PhD, within the CDC's Division of Research, Analysis, and Practice Integration, National Center for Injury Prevention and Control, regarding the impact of unit-dose packaging of buprenorphine products on pediatric exposure and the findings addressed in the October 21, 2016 publication titled, "Pediatric Emergency Department Visits for Buprenorphine/Naloxone Ingestion – United States, 2008-2015"; and

- (5) The records reflecting analysis completed and action taken by the CDC participants in the "Prevention of Overdoses & Treatment Errors in Children Taskforce" ("PROTECT") regarding the implementation of unit-dose packaging to reduce rates of pediatric exposure. Included among these records will be all materials reflecting the preparation for the November 1-2, 2012 CDC-sponsored PROTECT meeting.

These requests are tied directly to the known statements made by CDC employees in the 2016 publication and, with regard to the PROTECT-related request, the statements Dr. Budnitz made during his interview with the government earlier this year.

In addition, Indivior is requesting:

- (6) The records reflecting the CDC's analysis underlying its March 2016 recommendation reflected in its Guideline for Prescribing Opioids for Chronic Pain that "[c]linicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder."

Here again, Indivior's request is tied directly to a specific statement published by the CDC reflecting its recommendation regarding the use of buprenorphine to treat patients with opioid use disorder.[18] As with the statements from the FDA reflecting its support for the expanded development and utilization of buprenorphine treatments, this recommendation from the CDC is a relevant part of the larger story about the treatments Indivior has developed, and an essential

[18] *See* Deborah Dowell, et al., Centers for Disease Control and Prevention, CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016, 65 Morbidity & Mortality Wkly. Rep. 1 (2016).

aspect of Indivior's defense in this case.

V. Subpoena Directed to the National Institute on Drug Abuse ("NIDA")

Similar to the requests directed to the FDA and CDC, Indivior is requesting in the subpoena directed to NIDA (Exhibit E):

- (2) The records reflecting and supporting NIDA's position, as reflected in its Research Report addressing "Medications to Treat Opioid Use Disorder" issued in 2018 that buprenorphine and other medications used to treat opioid dependence "could help many people recover from opioid use disorder, but they remain highly underutilized";

- (3) The records reflecting and supporting NIDA's statement in its April 2012 "Medication-Assisted Treatment for Opioid Addiction" publication that "Scientific research has established that medication-assisted treatment of opioid addiction increases patient retention and decreases drug use, infectious disease transmission, and criminal activity"; and

- (4) The records reflecting and supporting NIDA employee Nora D. Volkow, M.D.'s statement in the New England Journal of Medicine Article titled "Medication-Assisted Therapies—Tackling the Opioid-Overdose Epidemic" and published on May 29, 2014 that "[e]xpanding access to MATs is a crucial component of the effort to help patients recover."

As with the requests directed to the other agencies, each of these requests is narrowly tailored based on statements in publicly available materials regarding NIDA's views on the underutilization and benefits of, and need for expanded access to, medication-assisted treatment for opioid dependence.[19] Again, these materials are highly relevant to Indivior's defense of its mission to provide effective outpatient treatment to patients struggling with opioid addiction. Rather than viewing these pharmaceuticals as contributing to the opioid epidemic, NIDA and other agencies have repeatedly endorsed and promoted expanded access to the treatments Indivior has developed.

[19] *See* Nat'l Inst. on Drug Abuse, Medications to Treat Opioid Use Disorder, Research Report Series (2018); Nat'l Inst. on Drug Abuse, Topics in Brief: Medication-Assisted Treatment for Opioid Addiction (2012); Nora D. Volkow, et al., Medication-Assisted Therapies—Tackling the Opioid-Overdose Epidemic, New Eng. J. Med. (2014).

In fact, it was NIDA that in the first instance worked with RBPI (then known as Reckitt & Colman) "to cooperatively design and perform the necessary research and cooperatively analyze the data generated to develop and attempt to gain FDA approval of two buprenorphine products for the treatment of opioid dependence."[20] Because of that, Indivior is also requesting from NIDA:

- (1) The records reflecting NIDA's efforts to collaborate with Reckitt Benckiser Pharmaceuticals Inc. (then known as Reckitt & Colman) in and around 1994 to develop buprenorphine products for the treatment of opioid dependence.

Here again, the requested records will reflect NIDA's view of the importance of the treatments Indivior has developed and further bolster Indivior's defense of its mission.

VI. Subpoenas Directed to Key State Agencies in Virginia, Tennessee, Kentucky, and Pennsylvania

Finally, Indivior is seeking from six state agencies the key records mirroring those it is requesting from DEA and SAMHSA regarding the same seven physicians that the government will allege engaged in careless prescribing practices. These requests are again tied directly to the government's claim in the Indictment that Indivior somehow aided and abetted certain physicians in prescribing and dispensing Suboxone Film in a "careless and clinically unwarranted manner." *See* Indictment ¶ 31, p. 26, ¶¶ 97-143. Each of the proposed subpoenas is directed to the agency responsible for overseeing the practice of medicine or the practice of pharmacy in the state in which one or more of the seven physicians were granted licenses and for taking disciplinary or corrective action against the individuals it regulates. These subpoena recipients include:

[20] Christian Heidbreder, et al., Indivior: pioneering research and development in the treatment of addictions (June 2015), *available* at https://www.nature.com/nature/outlook/addiction/pdf/Indivior.pdf (addressing the Cooperative Research and Development Agreement signed by NIDA and Reckitt & Colman in April 1994 to develop buprenorphine products for the treatment of opioid dependence).

- The Virginia Department of Health Professions, which encompasses the Virginia Board of Medicine and the Virginia Board of Pharmacy (Exhibit F);
- The Tennessee Health Related Boards, which encompasses the Tennessee Board of Medical Examiners and the Tennessee Board of Pharmacy (Exhibit G);
- The Kentucky Board of Medical Licensure (Exhibit H);
- The Kentucky Board of Pharmacy (Exhibit I);
- The Pennsylvania State Board of Medicine (Exhibit J); and
- The Pennsylvania State Board of Pharmacy (Exhibit K).

In each subpoena, Indivior is requesting the complete file for the relevant doctor, including all records relating to any audit or investigation of and any disciplinary action taken against the doctor, any reports submitted by pharmacies regarding prescriptions written by the doctor, any other complaints submitted to the agency about the doctor, and any reports of adverse events including, but not limited to, reports of overdoses associated with the doctor.

Like the records Indivior is requesting from the DEA and SAMHSA, any action or inaction by these agencies with respect to each of the physicians, which will be reflected in the requested files, is highly relevant to the question of the propriety of the physicians' prescribing practices and thus, critical to Indivior's defense. Indivior has again specifically targeted these requests to a narrow set of physicians, including the four physicians listed as Doctors A through D in the Indictment.

CONCLUSION

For the foregoing reasons, Indivior respectfully requests that the Court grant its Motion and issue the subpoenas attached as Exhibits A-K, requiring the return of the requested documents to undersigned defense counsel for inspection by December 30, 2019.

Dated: November 20, 2019

Respectfully submitted,

INDIVIOR INC. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.) and INDIVIOR PLC

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CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing to be presented to the Clerk of the Court for filing and uploading to the CM/ECF system, which will send notification of such filing to all counsel of record, on this 20th day of November, 2019.

/s/ Thomas J. Bondurant, Jr.
Counsel for Defendants